PATENT
Customer No. 22,852
Attorney Docket No. 09963.0008

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
BERNARD BARLAAM	)	Group Art Unit: 4161
	)	
Application No.: 10/571,991	)	Examiner: Willis, Douglas M.
	)	
Filed: March 15, 2006	)	Confirmation No.: 5523
	)	
For: QUINAZOLINE DERIVATIVES	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

SUBSTANCE OF INTERVIEW UNDER 37 C.F.R. § 1.133(B)

Further to the Interview on March 5, 2009, and the Examiner's Interview Summary mailed March 18, 2009, Applicants are submitting a recordation of the Substance of the Interview.

M.P.E.P. § 713.04 provides eight items (A-H) that should be addressed in Applicants' submission of the substance of the interview. Applicants' submissions regarding each of those items follow.

(A) The Exhibit shown at the interview is attached hereto as Exhibit A.

(B) The claims were generally all discussed.

(C) The prior art discussed, Bradbury (WO 03/082831), is identified in the attached Exhibit A.

(D) The Interview Summary indicates that "Applicant provided a presentation which included a proposed set of new claims to be filed by way of an RCE." However,

there was some degree of misunderstanding as Applicants' representatives merely indicated that the non-elected claims would be cancelled in an RCE, as required by the Office in the final Office Action, but that the elected claims 38-43 would be re-presented without amendment.

(E) The arguments discussed are provided in the attached Exhibit A. Furthermore, during the interview, the issue of obviousness-type double patenting of the pending claims in view of the pending claims in Bradbury Application No. 12/147,250 (the currently-pending continuation of the U.S. national phase application of WO 03/082831) and Example 11 thereof was raised. Applicants disagreed that there is an issue of obviousness-type double patenting.

Also discussed during the interview was the issue of interference estoppel in view of Applicants' lost counts of Interference Nos. 105,595 and 105,596. Applicants disagreed that there is any issue of interference estoppel.

(F) The pertinent matters discussed are provided in the attached Exhibit A.

(G) No agreement was reached at the interview.

(H) This interview was in person, so this item does not apply.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Jill MacAlpine

Dated: April 3, 2009

By: Jill MacAlpine, Reg. No. 60,475 for
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U.S. Application No. 10/571,991
Interview March 5, 2009

U.S. Application No. 10/571,991

Claims: Claims 38-71 are pending

- **Claims 44-71 are withdrawn from consideration**
- **Claims 38-43 are rejected**

Status: Final Office Action mailed 01/06/2009

- **§ 103(a) rejection over WO 03/082831 ("Bradbury")**

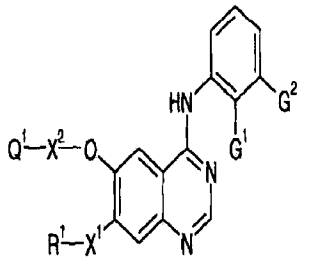
NO INTERFERENCE ESTOPPEL

All continuation claims are patentably distinct from the lost interference counts and all claims (lost claims) corresponding to those counts

'991 Claim 38 is Patentably Distinct Over Lost AZ Interference Claim 23 (Alternative Part of the Lost Count)

SUBSTITUENTS IN BLACK ARE IN LOST INTERFERENCE AZ CLAIM 23 (ALTERNATIVE PART OF LOST COUNT) BUT NOT IN NARROWER CLAIM 38

Claim 23. A quinazoline derivative of the Formula I:



wherein:
G^1 and G^2 each independently is halogeno;
X^1 is a direct bond or O;
R^1 is (1-6C)alkyl, wherein the (1-6C)alkyl group is optionally substituted by one or more substituents, which may be the same or different, selected from hydroxy, and/or a substituent selected from amino, (1-6C)alkoxy, (1-6C)alkylamino, di-[(1-6C)alkyl]amino, (2-6C)alkanoylamino, and (1-6C)alkanesulphonylamino;
X^2 is a direct bond;
Q^1 is (3-7C)cycloalkyl or heterocyclyl, wherein Q^1 optionally bears 1, 2, or 3 substituents, which may be the same or different, selected from cyano, amino, carbamoyl, (1-6C)alkyl, (1-6C)alkylsulphonyl, (1-6C)alkylamino, di-[(1-6C)alkyl]amino, N-(1-6C)alkylcarbamoyl, N,N-di-[(1-6C)alkyl]carbamoyl, (2-6C)alkanoyl, (2-6C)alkanoylamino, N-(1-6C)alkyl(2-6C)alkanoylamino, sulphamoyl, N-(1-6C)alkylsulphamoyl, N,N-di[(1-6C)alkyl]sulphamoyl, (1-6C)alkanesulfonylamino, N-(1-6C)alkyl-(1-6C)alkanesulfonylamino, carbamoyl(1-6C)alkyl, N-(1-6C)alkylcarbamoyl(1-6C)alkyl, N,N-di-[(1-6C)alkyl]carbamoyl(1-6C)alkyl, and (2-6C)alkanoylamino(1-6C)alkyl, and
wherein any (1-6C)alkyl and (2-6C)alkanoyl group within Q^1 optionally bears one or more substituents, which may be the same or different, selected from halogeno and hydroxy, and/or optionally a substituent selected from (1-6C)alkoxy and NR^aR^b, wherein R^a is hydrogen or (1-4C)alkyl and R^b is hydrogen or (1-4C)alkyl, or R^a and R^b together with the nitrogen atom to which they are attached form a 5 or 6 membered ring, which optionally bears 1 or 2 substituents on an available ring carbon atom selected from (1-4C)alkyl;
and wherein any heterocyclyl group within the Q^1-X^2- group optionally bears 1 oxo (=O) substituent;
or a pharmaceutically acceptable salt thereof.

'991 Claim 38 is Patentably Distinct Over Lost Interference AZ Claims 24 and 25

Lost AZ Interference Claim 24 (composition claim) and Lost AZ Interference Claim 25 (method claim) are of the same scope as Lost AZ Interference Claim 23 with respect to the compound or salt

Therefore '991 claim 38 is patentably distinct over Lost AZ Interference Claims 24 and 25 for the same reasons it is patentably distinct over Lost AZ Interference Claim 23

'991 Claims 39-43 are Patentably Distinct Over Lost AZ Interference Claims 23-25

'991 Claims 39-43 are no broader in compound or salt scope than '991 Claim 38

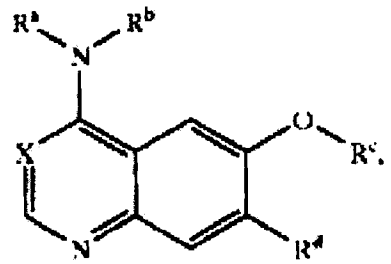
Those claims are patentably distinct for the same reasons that '991 Claim 38 is patentably distinct over Lost AZ Interference Claims 23-25

'991 Claim 38 is Patentably Distinct From Lost BI Claim 1, Alternative Part of the Lost Count

SUBSTITUENTS IN BLACK ARE IN LOST BI INTERFERENCE CLAIM 1 (ALTERNATIVE PART OF LOST COUNT) BUT NOT IN '991 CLAIM 38

1. A compound of the general formula

(I)



wherein
R^a denotes a hydrogen atom or a C1-4-alkyl group,

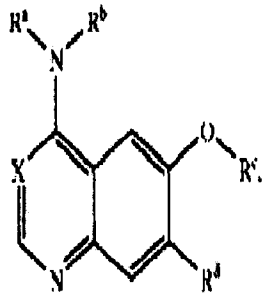
R^b denotes a phenyl or 1-phenylethyl group, wherein the phenyl nucleus is substituted in each case by the groups R^1 to R^3, while

R^1 and R^2, which may be identical or different, in each case denote a hydrogen, fluorine, chlorine, bromine or iodine atom, a C1-4-alkyl, hydroxy, C1-4-alkoxy, C2-3-alkenyl or C2-3-alkynyl group, an aryl, aryloxy, arylmethyl or arylmethoxy group, a heteroaryl, heteroaryloxy, heteroarylmethyl or heteroarylmethoxy group, a methyl or methoxy group substituted by 1 to 3 fluorine atoms or a cyano, nitro or amino group, and

R^3 denotes a hydrogen, fluorine, chlorine or bromine atom or a methyl or trifluoromethyl group,

Claim 1 of BI patent (cont'd)

II)



wherein

...Rc denotes

- a cyclobutyl, cyclopentyl or cyclohexyl group which is substituted in each case by a group R4-N-R5, while

R4 denotes a hydrogen atom or a C1-3-alkyl group and

R5 denotes a hydrogen atom or a C1-3-alkyl group,

an aminocarbonyl-C1-3-alkyl, C1-3-alkylaminocarbonyl-C1-3-alkyl, di-(C1-3-alkyl)aminocarbonyl-C1-3-alkyl, pyrrolidin-1-ylcarbonyl-C1-3-alkyl, piperidin-1-ylcarbonyl-C1-3-alkyl, homopiperidin-1-ylcarbonyl-C1-3-alkyl, morpholin-4-ylcarbonyl-C1-3-alkyl, homomorpholin-4-ylcarbonyl-C1-3-alkyl, piperazin-1-ylcarbonyl-C1-3-alkyl, 4-C1-3-alkyl-piperazin-1-ylcarbonyl-C1-3-alkyl, homopiperazin-1-ylcarbonyl-C1-3-alkyl or a 4-C1-3-alkyl-homopiperazin-1-ylcarbonyl-C1-3-alkyl group,

a hydroxy-C2-4-alkyl, C1-3-alkyloxy-C2-4-alkyl, C1-4-alkyloxy-carbonylamino-C2-4-alkyl, amino-C2-4-alkyl, C1-3-alkylamino-C2-4-alkyl, di-(C1-3-alkyl)amino-C2-4-alkyl, C1-3-alkylcarbonylamino-C2-4-alkyl, aminocarbonylamino-C2-4-alkyl, C1-3-alkylaminocarbonylamino-C2-4-alkyl, di-(C1-3-alkyl)amino-carbonylamino-C2-4-alkyl, pyrrolidin-1-ylcarbonylamino-C2-4-alkyl, piperidin-1-ylcarbonylamino-C2-4-alkyl, morpholin-4-ylcarbonylamino-C2-4-alkyl, C1-3-alkylsulphonyl-C2-4-alkyl or a C1-3-alkylsulphonylamino-C2-4-alkyl group,

a (2-oxo-pyrrolidin-1-yl)-C2-4-alkyl, (2-oxopiperidin-1-yl)-C2-4-alkyl, (3-oxo-morpholin-4-yl)-C2-4-alkyl, (2-oxo-imidazolidin-1-yl)-C2-4-alkyl, (2-oxo-3-C1-3-alkyl-imidazolidin-1-yl)-C2-4-alkyl, (2-oxo-hexahydropyrimidin-1-yl)-C2-4-alkyl or a (2-oxo-3-C1-3-alkyl-hexahydropyrimidin-1-yl)-C2-4-alkyl group,

a C1-4-alkylsulphonyl, chloro-C1-4-alkylsulphonyl, bromo-C1-4-alkylsulphonyl, amino-C1-4-alkylsulphonyl, C1-3-alkylamino-C1-4-alkylsulphonyl, di-(C1-3-alkyl)amino-C1-4-alkylsulphonyl, (pyrrolidin-1-yl)-C1-4-alkylsulphonyl, (piperidin-1-yl)-C1-4-alkylsulphonyl, (homopiperidin-1-yl)-C1-4-alkylsulphonyl, (morpholin-4-yl)-C1-4-alkylsulphonyl, (homomorpholin-4-yl)-C1-4-alkylsulphonyl, (piperazin-1-yl)-C1-4-alkylsulphonyl, (4-C1-3-alkyl-piperazin-1-yl)-C1-4-alkylsulphonyl, (homopiperazin-1-yl)-C1-4-alkylsulphonyl or a (4-C1-3-alkyl-homopiperazin-1-yl)-C1-4-alkylsulphonyl group, a C1-4-alkyloxycarbonyl group,

a formyl, C1-4-alkyl-carbonyl, C1-3-alkyloxy-C1-4-alkyl-carbonyl, tetrahydrofuranylcarbonyl, tetrahydropyranylcarbonyl, amino-C1-4-alkyl-carbonyl, C1-3-alkylamino-C1-4-alkyl-carbonyl, di-(C1-3-alkyl)amino-C1-4-alkyl-carbonyl, pyrrolidin-1-yl-C1-4-alkyl-carbonyl, piperidin-1-yl-C1-4-alkyl-carbonyl, (homopiperidin-1-yl)-C1-4-alkyl-carbonyl, morpholin-4-yl-C1-4-alkyl-carbonyl, (homomorpholin-4-yl)-C1-4-alkyl-carbonyl, (piperazin-1-yl)-C1-4-alkyl-carbonyl, (4-C1-3-alkyl-piperazin-1-yl)-C1-4-alkyl-carbonyl, (homopiperazin-1-yl)-C1-4-alkyl-carbonyl, (4-C1-3-alkyl-homopiperazin-1-yl)-C1-4-alkyl-carbonyl or a C1-3-alkylsulphonyl-C1-4-alkyl-carbonyl group,

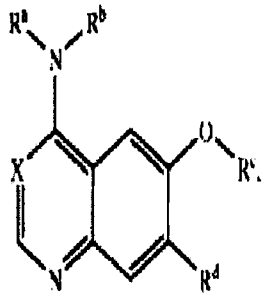
a cyano, aminocarbonyl, C1-3-alkyl-aminocarbonyl, di-(C1-3-alkyl)aminocarbonyl, (C1-3-alkyloxy-C2-4-alkyl)aminocarbonyl, N-(C1-3-alkyl)-N-(C1-3-alkyloxy-C2-4-alkyl)aminocarbonyl, arylaminocarbonyl, pyrrolidin-1-ylcarbonyl, piperidin-1-ylcarbonyl, homopiperidin-1-ylcarbonyl, morpholin-4-ylcarbonyl, homomorpholin-4-ylcarbonyl, 2-oxa-5-aza-bicyclo[2.2.1]hept-5-ylcarbonyl, 3-oxa-8-aza-bicyclo[3.2.1]oct-8-ylcarbonyl, 8-oxa-3-aza-bicyclo[3.2.1]oct-3-ylcarbonyl, piperazin-1-ylcarbonyl, 4-C1-3-alkyl-piperazin-1-ylcarbonyl, homopiperazin-1-ylcarbonyl, 4-C1-3-alkyl-homopiperazin-1-ylcarbonyl, aminosulphonyl, C1-3-alkyl-aminosulphonyl, di-(C1-3-alkyl)amino-sulphonyl, pyrrolidin-1-yl-sulphonyl, piperidin-1-ylsulphonyl, homopiperidin-1-ylsulphonyl, morpholin-4-ylsulphonyl, homomorpholin-4-ylsulphonyl, piperazin-1-ylsulphonyl, 4-C1-3-alkyl-piperazin-1-ylsulphonyl, homopiperazin-1-ylsulphonyl or a 4-C1-3-alkyl-homopiperazin-1-ylsulphonyl group,

a cyclobutyl, cyclopentyl or cyclohexyl group which is substituted in each case by a group R6, where R6 denotes a 2-oxo-pyrrolidin-1-yl, 2-oxopiperidin-1-yl, 3-oxo-morpholin-4-yl, 2-oxo-imidazolidin-1-yl, 2-oxo-3-C1-3-alkyl-imidazoldin-1-yl, 2-oxo-hexahydropyrimidin-1-yl or a 2-oxo-3-C1-3-alkyl-hexahydropyrimidin-1-yl group,

- an azetidin-3-yl group which is substituted in the 1 position by the group R5, while R5 is as hereinbefore defined,
- a pyrrolidin-3-yl group which is substituted in the 1 position by the group R5, while R5 is as hereinbefore defined,
- a piperidin-3-yl group which is substituted in the 1 position by the group R5, while R5 is as hereinbefore defined,
- a piperidin-4-yl group which is substituted in the 1 position by the group R5, while R5 is as hereinbefore defined, or
- a tetrahydrofuran-3-yl, tetrahydropyran-3-yl or tetrahydropyran-4-yl group,

Claim 1 of BI patent (cont'd)

(I)



wherein

...R^d denotes

a hydrogen atom or a fluorine, chlorine or bromine atom,

a hydroxy group,

a C1-4-alkyloxy group,

a methoxy group substituted by 1 to 3 fluorine atoms,

an ethyloxy group substituted by 1 to 5 fluorine atoms,

a C2-4-alkyloxy group which is substituted by a group R6 or R7, while

R6 is as hereinbefore defined and R7 denotes a hydroxy, C1-3-alkyloxy, C1-3-cycloalkyloxy, amino, C1-3-alkylamino, di-(C1-3-alkyl)amino, bis-(2-methoxyethyl)-amino, pyrrolidin-1-yl, piperidin-1-yl, homopiperidin-1-yl, morpholin-4-yl, homomorpholin-4-yl, 2-oxa-5-aza-bicyclo[2.2.1]hept-5-yl, 3-oxa-8-aza-bicyclo[3.2.1]oct-8-yl, 8-oxa-3-aza-bicyclo[3.2.1]oct-3-yl, piperazin-1-yl, 4-C1-3-alkyl-piperazin-1-yl, homopiperazin-1-yl or C1-3-alkyl-homopiperazin-1-yl group, or a formylamino, C1-3-alkylcarbonylamino, C1-3-alkyloxy-C1-3-alkyl-carbonylamino, C1-4-alkyloxycarbonylamino, aminocarbonylamino, C1-3-alkylaminocarbonylamino, di-(C1-3-alkyl)aminocarbonylamino pyrrolidin-1-ylcarbonylamino, piperidin-1-ylcarbonylamino, piperazin-1-ylcarbonylamino, 4-C1-3-alkyl-piperazin-1-ylcarbonylamino, morpholin-4-ylcarbonylamino or a C1-4-alkylsulphonylamino group,

a C3-7-cycloalkyloxy or C3-7-cycloalkyl-C1-4-alkyloxy group,

a tetrahydrofuran-3-yloxy, tetrahydropyran-3-yloxy or tetrahydropyran-4-yloxy group,

a tetrahydrofuranyl-C1-4-alkyloxy or tetrahydropyranyl-C1-4-alkyloxy group,

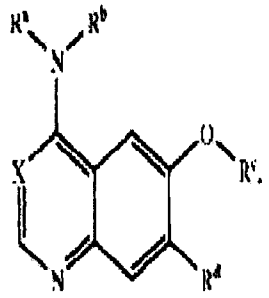
a C1-4-alkoxy group which is substituted by a pyrrolidinyl, piperidinyl or homopiperidinyl group substituted in the 1 position by the group R8, while

R8 denotes a hydrogen atom or a C1-3-alkyl group,

or a C1-4-alkoxy group which is substituted by a morpholinyl group substituted in the 4 position by the group R8, while R8 is as hereinbefore defined, and

Claim 1 of BI patent (cont'd)

(I)



wherein
...X denotes a nitrogen atom, and

by the aryl groups mentioned in the definition of the above groups is meant in each case a phenyl group which is mono- or disubstituted by R9, while the substituents may be identical or different and R9 denotes a hydrogen atom, a fluorine, chlorine, bromine or iodine atom or a C1-3-alkyl, hydroxy, C1-3-alkyloxy, difluoromethyl, trifluoromethyl, difluoromethoxy, trifluoromethoxy or cyano group,

by the heteroaryl groups mentioned in the definition of the above groups is meant a pyridyl, pyridazinyl, pyrimidinyl or pyrazinyl group, while said heteroaryl groups are each mono- or disubstituted by the group R9, while the substituents may be identical or different and R9 is as hereinbefore defined, and

said pyrrolidinyl, piperidinyl, piperazinyl and morpholinyl groups may be substituted in each case by one or two C1-3-alkyl groups, and

unless otherwise stated, said alkyl groups may be straight-chained or branched,

with the proviso that the compound 4-[(3-chloro-4-fluoro-phenyl)amino]-6((S)-tetrahydrofuran-3-yloxy)-7-hydroxy-quinazoline is excluded,

their tautomers, their stereoisomers, their mixtures and their salts.

'991 Claims 39-43 are Patentably Distinct over Lost BI Claims 3-6

Lost BI Claim 3-5 are drawn to 3- or 3,4- substitution on the phenyl ring

Lost BI claim 6 is drawn to 3,4- substitution on the phenyl ring

In contrast, '991 Claims 39-43 all recite 2,3-substitution on the phenyl ring

U.S. Application No. 10/571,991

Response:

Bradbury is not applicable prior art under 103(c) since Bradbury and the claimed invention were, at the time the invention was made, subject to an obligation of assignment to AstraZeneca.

U.S. Application No. 10/571,991

Bradbury: Effective U.S. filing date is March 26, 2003 (PCT filing date)

Present application: Priority claimed to EP03292309.6, filed September 19, 2003 (i.e., less than a year after Bradbury's date)

U.S. Application No. 10/571,991

Present Application:

Claims drawn to:

- A compound chosen from 4-(3-chloro-2-fluoroanilino)-7-methoxy-6-{[1-(carbamoylmethyl) piperidin-4-yl]-oxy}quinazoline and its pharmaceutically acceptable salts

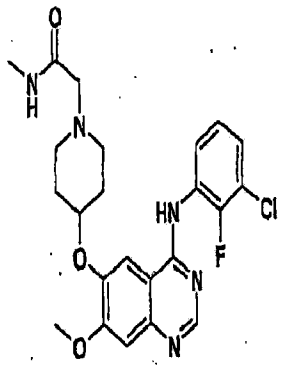
A pharmaceutical composition comprising at least one of compound chosen from 4-(3-chloro-2-fluoroanilino)-7-methoxy-6-{[1-(carbamoylmethyl) piperidin-4-yl]-oxy}quinazoline and its pharmaceutically acceptable salts
in association with a pharmaceutically-acceptable diluent or carrier

U.S. Application No. 10/571,991

Present application: Priority EP03292309.6 contains § 112 support for the present claims

Example 1

Preparation of 4-(3-Chloro-2-fluoroanilino)-7-methoxy-6-{[1-(N-methylcarbamoylmethyl)piperidin-4-yl]methoxy}quinazoline



2-Chloro-N-methylacetamide (32 mg, 0.3 mmol) was added dropwise to a mixture of 4-(3-chloro-2-fluoroanilino)-7-methoxy-6-[(piperidin-4-yl)oxy]quinazoline (120 mg, 0.3 mmol), potassium iodide (16 mg, 0.1 mmol), and potassium carbonate (50 mg, 0.36 mmol) in acetonitrile (5 ml). The mixture was heated at reflux for one hour. After evaporation of the solvents under vacuum, the residue was taken up in dichloromethane. The organic solution was washed with water and brine, dried over magnesium sulfate. After evaporation of the solvents under vacuum, the residue was purified by chromatography on silica gel (eluant: 1% to 2% 7N methanolic ammonia in dichloromethane) to give the title compound as a white solid (85 mg, 60%).

U.S. Application No. 10/571,991

Present application: Priority EP03292309.6 contains § 112 support for the present claims

19. A pharmaceutical composition which comprises a quinazoline derivative of the Formula I, or a pharmaceutically-acceptable salt thereof, as defined in any one of claims 1 to 17 in association with a pharmaceutically-acceptable diluent or carrier.